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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,138	07/24/2003	Brian Guth	1/1370	9348

28501 7590 07/14/2005

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,138	GUTH ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 3/17/2005 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 2-3 have been canceled.

2. New Claims 15-20 have been added.

3. Claims 1, 7 and 13 have been amended.

4. Remarks drawn to rejections under 35 USC 112, first paragraph, 103 and double patenting.

Claims 1 and 4-20 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Objections

The objection to claim 14 has been overcome by amendment.

Claim Rejections - 35 USC § 112

Claims 1 and 4-20 are rejected under 35 U.S.C. 112, first paragraph as non-enabling for the prevention of heart failure has been overcome by deletion of the term prevention in claim 1.

Double Patenting

Claims 1 and 4-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10 and 14 of copending Application No. 10/257,481 ('481 application) is being maintained for reasons of record.

Applicants argue that myocardial disease is not the same as heart failure. Since the claim does not define myocardial disease and according to Merck Manual heart failure is a clinical manifestation of myocardial hypertrophy a substantial overlap of limitations between the instant claims and claims of the copending '481 patent is seen.

Claim Rejections - 35 USC § 103

Claims 1 and 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Psiorz et al (US 5,175,157) in combination with and Rieu et al (Eur. J. Med. Chem., 1993, 28, 683-691), The Merck Manual (1987, Fifteenth Edition, pp 519-521), Bergeron (US 6083991), Hodges et al (US 5308853), Kleeman (US 5,968,978) and Liu (US 5,721,217) is being maintained for reasons of record.

Applicants argue that:

1. Psiorz et al discloses cilobradine as a cardioactive substance which reduces heart rate and has the effect of reducing the oxygen requirement of the heart and that it fails to teach the use of cilobradine to treat heart failure.

2. Rieu et al, Merck manual, Bergeron and Hodges et al do not fill the gap between Psiorz and the instant claims.

This is not found to be persuasive.

The instant claims are drawn to a method of treatment of heart failure. Heart failure is not further defined by the claim. Hence an abnormal functioning of the heart is seen as heart failure.

Psiorz et al teach the use of cilobradine as a cardioactive agent that lowers heart rate. This means that the heart rate is irregular. Rieu mentions cilobradine with reference to bradycardiac agents i.e. an agent that helps maintain regular heart beat or an agent that rectifies irregular heart beat with not toxic side effects. According to the Merck manual palpitations or irregular pulsation of the heart leads to heart failure. Even though it may occur less often according to Merck Manual it is still a condition that could manifest as a result of palpitations. Bergeron teaches the use of vasodialators, ACE inhibitors and cardioglycosides for the treatment of cardiac arrhythmias (irregular heart beat). Kleeman teaches the use of diuretics, cardioglycosides, ACE inhibitors, ARB's and beta-blockers for treatment of heart failure. Hence the prior art in combination suggest the use of cilobradine for the treatment of heart failure (irregular heart functioning). Since cilobradine is taught to be used for maintaining regular heart beat by Psiorz (reducing heart rate if it is high) with no toxic side effects (col. 37, lines 24-25) and is taught (Rieu) to have no negative inotropic (affecting the force of muscular contraction) or hypotensive (low blood pressure) effect and since irregular pulsation of the heart leads to heart failure (Merck) one of ordinary skill in the art would be motivated to use cilobradine for the treatment of heart failure.

Conclusion

Claims 1 and 4-20 are rejected

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

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SUPERVISORY PATENT EXAMINER
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